No. 84-162

In the Supreme Court of the United States

OCTOBER TERM, 1983

AN ARTICLE OF DEVICE: "TOFTNESS RADIATION DETECTOR," TOFTNESS POST-GRADUATE SCHOOL OF CHIROPRACTIC, INC., a corporation, and IRWING N. TOFTNESS, an individual,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

E. CAMPION KERSTEN
c/o KERSTEN & McKINNON
231 West Wisconsin Avenue
Milwaukee, Wisconsin 53203
(414) 271-0054
Attorney for Petitioners

UNITED STATES LAW PRINTING CO., CHICAGO, ILLINOIS 60618 (312) 525-6581

QUESTION PRESENTED FOR REVIEW

In the absence of authority from Congress, may the Food and Drug Administration cause the burden of proof in "misbranding" cases involving prescription devices brought in the district courts under the Food, Drug and Cosmetic Act of 1938 to be shifted to the defendant merely by so structuring its rules as to make the labeling requirements for prescription devices appear to be an "exemption" from the labeling requirements for over-the-counter devices?

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REFERENCE TO REPORTS OF OPINIONS BELOW

The opinion of the court of appeals is reported at 731 F.2d 1253 and is reproduced at App. 1 *et seq.* The opinion of the district court is not reported and is reproduced at App. 21 *et seq.*

* The petitioner corporation has no parent or subsidiary corporation.

JURISDICTION

The judgment of the court of appeals was entered on April 4, 1984. App. 33. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 321(h) [Section 201 (h), Food, Drug and Cosmetic Act of 1938]

> The term "device" . . . means an instrument, apparatus, implement, . . . or other similar or related article, . . . which is—
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> * * *
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

21 U.S.C. § 352. Misbranded drugs and devices [Section 502, Food Drug and Cosmetic Act of 1938]

> A drug or device shall be deemed to be misbranded—
>
> (f) Unless its labeling bears (1) adequate directions for use . . . . *Provided,* That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 C.F.R. 801.5 Medical Devices; adequate directions for use

"Adequate directions for use" means directions under which the layman can use a device safely and for the purposes for which it is intended.

21 C.F.R. 801.109 Prescription devices

A device . . . shall be exempt from section 502(f)(1) of the act [21 U.S.C. § 352(f)(1)] if all the following conditions are met:

(a) The device is:

* * * * *

(1)(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device . . . bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a .....", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device: and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the

purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

* * *

STATEMENT OF THE CASE

A. Nature of the case, course of proceedings and disposition in the courts below.

This is an action for condemnation and forfeiture by the United States Government, in behalf of the Food and Drug Administration (FDA), against the Toftness Radiation Detector (TRD). The government alleges that the TRD is "misbranded" under 21 U.S.C. §352(f)(1), a provision of the Federal Food, Drug, and Cosmetic Act of 1938 ("the Act"). It sought condemnation of two TRD's that had been seized and injunction against further manufacture and use of the instrument.

The jurisdiction of the district court was invoked under 21 U.S.C. § 334 and 28 U.S.C. § 1345. The United States District Court for the Western District of Wisconsin, the Honorable Robert W. Warren presiding, entered judgment for the government following a jury verdict. The United States Court of Appeals for the Seventh Circuit affirmed on April 4, 1984, having jurisdiction of the appeal under 28 U.S.C. § 1291.

The district court held and instructed the jury that the defendants (petitioners here) had the burden to prove the TRD is not misbranded by proving that it worked and that suitable instructions for use could therefore be written for it. App. 43 to 45.

The jury returned a general verdict in favor of the government. Judgment was entered on the verdict on January 18, 1982 condemning the seized instruments and enjoining their further manufacture and use. App. 34 to 37.

Defendants' motion for a new trial was denied by a written decision entered on January 18, 1983. App. 21.

On April 4, 1984 the United States Court of Appeals for the Seventh Circuit affirmed the judgment. 731 F.2d 1253; App. 1 to 20. This petition is filed to seek review of the decision and judgment of the court of appeals.

B. Statement of facts.

The Toftness Radiation Detector (TRD) is a completely passive research instrument designed to collect and focus low-level electromagnetic radiation emitted from the body. Its proponents claim it aids in sensing differentials in the intensity of radiation that correlate with areas of neurological stress in the body that can then, in some cases, be alleviated by customary chiropractic methods.

The TRD consists of a plastic cylinder approximately ten inches long and three inches in diameter containing a series of lenses which focus radiation onto a detection plate at the top of the instrument.

It was substantially undisputed during the trial that the phenomenon of electromagnetic radiation from the human body is genuine; that low levels of electromagnetic radiation across most of the electromagnetic spectrum are emitted by the human body; that the level and intensity of this radiation increases in the presence of pathology and that such radiation is capable of being collected and focused through the use of lenses. Substantially the only area of factual dispute in the case was whether such focused radiation could be sensed by trained users of the TRD.

The patent on the TRD is held by the defendant Irwing N. Toftness, a doctor of chiropractic who resides and practices in Wisconsin. He is the founder and principle teacher at the Toftness Post-Graduate School of Chiropractic, an accredited post-graduate school.

Attendance at the Toftness Post-Graduate School is limited to licensed chiropractors. As of the time of trial approximately 1,000 chiropractors had attended the school. Most of these had also been instructed in the use of the TRD over a period of approximately three weeks, followed by three more years of practical training, for purposes of research and experimentation. Approximately 700 of them had signed leases for the instrument in which they agreed to use the instrument for research purposes only and to report back the results of their experiments and research. The proceeds of the lease arrangement were used to finance continuing research in chiropractic knowledge and methods and in further specific research on the TRD itself. Detailed written "instructions for use" were provided to users of the instrument from time to time, revised as called for by the ongoing research process.

The district court and the court of appeals accepted, albeit reluctantly (see App. 44-45 and App. 16, the following chain of reasoning propounded by the government:

1. Section 502(f) of the Act (21 U.S.C. § 352(f)) says that a device is misbranded if its labeling does not contain "adequate directions for use." See App. 10.

2. 21 C.F.R. § 801.5, promulgated by the FDA under the general rule-making authority of the Act, defines "adequate directions for use" to mean "directions under which the *layman* can use a device safely and for the purposes for which it is intended." (Emphasis supplied), *see, supra* at 3 and App. 10.

3. Directions suitable for laymen cannot be written for devices, such as the TRD, intended to be used only by licensed professionals and not by laymen—so-called prescription devices. Such devices are *ipso facto* "misbranded." See App. 10, 11.

4. Proponents of prescription devices can escape the charge of misbranding only by proving the device is "exempt" from the "adequate directions for lay use" requirement by proving compliance with the "prescription device" requirements of 21 C.F.R. § 801.109, specifically here the labeling provisions contained in subsection (c) which require that the device be accompanied by "information for use . . . under which [licensed] practitioners . . . can use the device safely and for the purposes for which it is intended. . . ." See App. 10, 11.

5. Under the foregoing rule, a prescription device is misbranded if it does not work. See App. 11.

6. Although the government ordinarily has the burden to prove misbranding (see App. 15), the proponent of a prescription device is forced by the structure of the FDA's foregoing rules to assert an *exemption from the "adequate instructions for lay use" requirement* and therefore has the burden to prove the device is not misbranded by proving compliance with the prescription device rule, in this case by proving the TRD works. See App. 15.

7. The burden of proof as to misbranding is thus shifted from the government to the proponent in every misbranding case involving a prescription device because of the way in which the FDA has structured its rules: making the labeling requirements for prescription devices an exception to or exemption from the labeling requirements for over-the-counter devices. See App. 15, 16.

The court of appeals acknowledged that the Food, Drug and Cosmetic Act and the regulations under it, as well as the history of the legislation and the regulations, provide no authority or reason for this shifting of the burden of

proof. See App. 13. There being no specific legislative or administrative authorization, the shifting of the burden of proof here results solely from the way in which the FDA has structured its rules (see App. 13, 15), even though the FDA could just as well have promulgated regulations which established separate sets of labeling requirements for prescription and over-the-counter devices which would not put proponents of prescription devices in the position of having to establish an "exemption" from labeling requirements that obviously do not pertain to them.

This petition raises the question of whether the rules of an administrative agency should be permitted to control procedures and substantive rights in the federal courts of the United States in such a manner in the absence of legislative authority.

ARGUMENT

I.

SPECIAL AND IMPORTANT REASONS EXIST WHY REVIEW ON WRIT OF CERTIORARI SHOULD BE GRANTED.

This Court should settle the question of whether an administrative agency can affect the application of the burden of proof in a district court civil action merely by structuring its rules in such a way as to put a defendant in the position of appearing to assert an "exemption" when in fact no true exemption is invoked.

The decision of the court of appeals shifting the burden of proof to the defendants (petitioners here) is not necessary or appropriate under the Food, Drug and Cosmetic Act of 1938, has not been otherwise authorized by Congress and is in conflict with the court of appeals for the Fifth Circuit on the question of whether the government retains the burden to prove misbranding even when prescription drugs or devices are involved.

II.

THE COURT OF APPEALS HAS GIVEN THE FOOD AND DRUG ADMINISTRATION UNWARRANTED POWER TO CONTROL THE APPLICATION OF THE BURDEN OF PROOF IN MISBRANDING CASES INVOLVING PRESCRIPTION DEVICES IN THE DISTRICT COURTS.

The position of the petitioners in the courts below was that the government has the burden to prove that a prescription medical device is misbranded, just as it has the burden to prove that an over-the-counter medical device

is misbranded. Petitioners have not argued and do not argue that the instrument involved in this case is exempt from any of the FDA regulations *pertaining to prescription devices.*

The court of appeals adopted the argument propounded by the government in the district court that a "prescription device" is misbranded if it lacks adequate instructions for use by lay persons and that the instrument could escape the charge of misbranding only if its proponents establish that the device comes within a so-called "exemption" from the labeling requirements applicable to over-the-counter devices, so that the burden of proof on misbranding shifts to the device and its proponents. Thus, instead of the government having the burden to prove a prescription device is misbranded, the proponent of such a device has now been held to have the burden of proof it is not misbranded.

No such shifting of the burden of proof was ever authorized by Congress, by this Court or by any other court, until the court of appeals did so in this case.

This case does not involve the question of whether Congress has the power to regulate the burden of proof applied in civil cases in the district court. It does not involve the power of an administrative agency to establish rules relating to the burden of proof in proceedings before the agency itself. Instead, it involves the question of whether an administrative agency, merely by the manner in which it structures its rules, can manipulate the burden of proof in the district courts.

In the absence of a clear expression by Congress that power has been delegated to the FDA or to any other agency, it should not be assumed that the mere structure of administrative rules can affect such fundamental judicial procedures as the burden of proof. This Court should

take jurisdiction to establish that proposition in order to preserve the proper relationship between administrative agencies and district courts and to forestall the kind of encroachment on the prerogatives of the district courts that the Seventh Circuit here appears to sanction.

The court of appeals agreed that the government generally has the burden to prove a charge of misbranding. App. 15. The court also held (App. 15) that the FDA's rules are framed to make the prescription device provisions an "exemption" from the general labeling requirements.

The court of appeals stated (App. 15) that there is no reason the FDA could not have structured its rules in a more logical way: that is, with separate sets of labeling requirements, one for prescription devices and one for over-the-counter devices. The court concluded (App. 15):

> Certainly the FDA could have promulgated regulations which would have established two categories of devices—prescription and over-the-counter—with two separate sets of labeling requirements. . . . Under such a hypothetical regulatory scheme, we would have little difficulty in holding that the government bore the burden of proving that the device did not satisfy the prescription device requirements. . . . Instead, the FDA promulgated the regulations actually before us, and those regulations make prescription devices one of several exemptions to the more general labeling requirements. *No purpose justifying this odd structure occurs to us other than the purpose of shifting the burden of proof.* By treating the large category of prescription devices under an exemption to the more general requirements, the FDA appears to have wanted to make its task somewhat easier by placing on claimants the burden of proving that their device is safe and is actually effective for its intended purposes. (Emphasis supplied).

Thus, the FDA has managed, for no clear or authorized reason, to shift the burden of proof in prescription device misbranding cases in the district courts merely by the technique of structuring its rules so as to make prescription device rules an exception to over-the-counter device rules.

The action of the court of appeals here is contrary to the position taken by the Fifth Circuit in *United States* v. *Evers,* 643 F.2d 1043 (5th Cir. 1981). In that case the FDA was attempting to establish misbranding by imposing upon a drug used only by the dispensing physician labeling requirements applicable to over-the-counter drugs, when the drug was not sold over-the-counter, and to prescription drugs, even though he did not make the drug available to other physicians. The court made clear (at 1053) that it is nonsensical and serves no legitimate purpose to impose labeling requirements on a drug which are not relevant to the class which will purchase the drug. It is just as nonsensical to say that a prescription device is misbranded if it lacks adequate instructions for lay use as it is to say a drug is misbranded, lacking any directions, when no directions are required under the circumstances.

The court of appeals is correct in stating (App. 13, n. 4) that the question of burden of proof was not directly at issue in the *Evers* case. Nevertheless, the fact that the burden of proof was on the government was specifically mentioned at least three times (at 1047, 1049, 1052), the court stating, "Since Calcium EDTA is a prescription drug, the FDA can establish an act of misbranding under section 502(f)(1) of the Act only by proving that Dr. Evers did not provide adequate information for use by physicians, as is required by the exceptions to that section." 643 F.2d at 1052.

The real significance of *Evers* is the necessity to determine *which* statutory scheme applies—over-the-counter or prescription or, as in that case, neither. It is only by overlooking this necessary distinction that the court of appeals here found it permissible for the FDA to effectively control the application of the burden of proof in the district court merely by the structuring of its rules in a particular way.

CONCLUSION

Based upon the foregoing considerations, petitioners respectfully request that a writ of certiorari issue to review the decision of the court of appeals.

Respectfully submitted,

E. CAMPION KERSTEN
Attorney for Petitioners

July 3, 1984

APPENDIX

In the

United States Court of Appeals

For the Seventh Circuit

No. 83-1404

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

AN ARTICLE OF DEVICE . . . "TOFTNESS RADIATION DETECTOR," TOFTNESS POST-GRADUATE SCHOOL OF CHIROPRACTIC, INC., a corporation, and IRWING N. TOFTNESS, an individual,

Defendants-Appellants.

Appeal from the United States District Court for the Western District of Wisconsin.

Nos. 75-C-478 & 75-C-479—Robert W. Warren, *Judge.*

ARGUED DECEMBER 7, 1983—DECIDED APRIL 4, 1984

Before CUDAHY, ESCHBACH and COFFEY, *Circuit Judges.*

CUDAHY, *Circuit Judge.* Under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act"), a prescription medical device is "misbranded" if it cannot be used safely and effectively for its intended purposes. The Toftness Radiation Detector ("TRD") is a chiropractic instrument which purportedly detects electromagnetic radiation from the human body and focuses that radiation so

that a chiropractor can detect conditions which require chiropractic treatment. The government sued to condemn the TRD as "misbranded" under the Act and to enjoin the TRD's inventor from producing, distributing or using the TRD. After a trial in the district court, a jury rendered a verdict for the government, and this appeal followed.

I

Defendant-appellant Irwing N. Toftness is a licensed chiropractor who practices in Cumberland, Wisconsin, and who invented the TRD. The TRD, which is patented, consists of a plastic cylinder containing a series of plastic lenses. According to Toftness, low levels of electromagnetic radiation emanate from the human body, and that radiation emanates most strongly from areas of neurological disturbance. The TRD is supposed to be capable of detecting and focusing this radiation through the plastic lenses. When a trained user holds the TRD close to a patient's skin, the user is supposed to detect this radiation by rubbing his or her fingers on the detection plate and feeling resistance to the movement of the fingers. After locating the points of disturbance, the chiropractor can then make adjustments to the body to alleviate these neurological disturbances.

Toftness is also the president of defendant-appellant Toftness Post-Graduate School of Chiropractic, Inc. Only licensed chiropractors who have completed a training course at the Toftness School may use the TRD. The course lasts several weeks and costs $400. At the time of the trial in this case, approximately 700 chiropractors had attended the TRD course and had signed leases for the TRD. The fifteen year leases of the instrument call for payment of $700 for the first year and $100 for each of the next fourteen years. The leases also provide that the

use of the instrument should be limited to research purposes and that the user should keep careful research records and forward those records to the school.

The government brought this action under the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301 *et seq.*, contending that the TRD is a "misbranded" device under 21 U.S.C. § 334 (a)(1). We shall explain the statutory and regulatory framework in more detail below, but the heart of the government's case is its contention that the TRD simply does not work and is therefore "misbranded." Government witnesses testified at trial that the TRD is incapable of detecting any radiation coming from the human body. Defense witnesses testified in turn about their experimental use of the TRD and their purported success in treating patients while using the TRD. The jury rendered a verdict for the government, and the district court denied the defendants' motion for a new trial.[1]

This appeal followed, and appellants here argue that the district court erred with respect to three issues. First, appellants contend that the district court improperly instructed the jury that the TRD was, as a matter of law, a "device" as defined in 21 U.S.C. § 321(h) and thus subject to the provisions of the Act. Second, appellants argue that the district court erroneously instructed the jury that the burden of proof was on the defendants to show that the TRD was properly labeled as a "prescription device" under 21 C.F.R. § 801.109 (1983). Third, they argue that

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[1] The instant action originated in the District of Oregon and was transferred by stipulation of the parties first to the Eastern District of Wisconsin and then to the Western District of Wisconsin. Judge Robert W. Warren of the Eastern District of Wisconsin presided at trial.

the court erred by instructing the jury not to "pile inference on inference." For the following reasons, we conclude that the district court did not err in these three matters and we affirm its judgment.

II

The first issue on appeal is whether the TRD is a "device" as defined in section 201(h) of the Act, 21 U.S.C. § 321(h), and thus subject to the Act's misbranding provisions. The district court instructed the jury that the TRD is a "device," and appellants contend that the district court erred in directing a verdict on this point. According to appellants, the TRD is not subject to the misbranding provisions because its intended uses are limited to research purposes. In our view the district court properly directed a verdict on this issue because the appellants' attempted rebuttal was based on a misreading of the Act. The Act's definition of "device" includes instruments used for research so long as the intended uses of the instrument in question include the diagnosis and treatment of diseases or other conditions.

To determine whether the TRD is a "device" under the Act, we begin with section 304(a)(1) of the Act, 21 U.S.C. § 334(a)(1), which permits the government to seize any misbranded "article of . . . device" in interstate commerce. Section 201(h) of the Act, 21 U.S.C. § 321(h), defines "device" to include:

> instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

The FDA has issued regulations which further elaborate on this definition by defining "intended uses." The regulations provide in relevant part:

> The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

21 C.F.R. § 801.4 (1983). The dispute here concerns the language: "use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321 (h)(1). Defendants appear to offer two distinct but closely related theories supporting their contention that the TRD does not fall within that definition of "device." First, they introduced evidence showing that the TRD was not intended to be used as the sole means of diagnosing patients or of evaluating the success of their treatments. Second, they introduced evidence tending to show that the TRD was intended only for research use instead of for diagnosis or treatment.

In response, the government refers us to evidence showing that the TRD was intended for use in the diagnosis and treatment of patients by chiropractors. That evidence includes the instructions that Dr. Toftness prepared for use of the TRD, the financial arrangements through which chiropractors were trained in the use of the TRD and permitted to use it and the testimony of the appellants' wit-

nesses showing that they had made chiropractic adjustments to patients on the basis of TRD readings. The instructions for the use of the TRD contain, in various versions, directions for sensing points of maximum radiation, for interpreting those radiation readings and for making appropriate chiropractic adjustments. The financial arrangements include the tuition for instruction in the proper use of the TRD and the fifteen year leases for the instrument itself. Further, several of appellants' witnesses testified that they had actually made chiropractic adjustments to patients based upon readings from the TRD and that they had measured the effectiveness of treatment through use of the TRD. That evidence supported appellants' contention that the TRD is "effective," *see infra* Part III, but it also supported the government's argument that the TRD is a "device."

On the other hand, the appellants point out that the instructions stated that the TRD was to be used only in conjunction with standard chiropractic techniques such as "Chiropractic Palpation" or "Line of Drive." The instructions also directed the user to keep careful records of all adjustments on "Daily Research Cards." There was, in addition, evidence showing that TRD users have not advertised that they use the TRD, that they have not charged patients more money for use of the TRD in diagnosis or treatment and that the users have informed patients that they were testing this new instrument. Appellants, based on this evidence, argue that the intended use of the TRD until now has been solely for research and that users have simply tested the device by using it and comparing their findings from its use against findings made using established techniques.

To avoid the directed verdict, appellants needed either to cast doubt on the government's evidence of intended

use or to introduce other evidence rebutting the government's evidence. However, the appellants stipulated to much of the evidence supporting the government's position, and they introduced some of it themselves.[2] It would have been impossible for any reasonable jury to have rejected this evidence. Therefore, to avoid the directed verdict, appellants rely on the evidence tending to show that the TRD was used only in conjunction with established chiropractic techniques and that the TRD was being used only for research. On appeal we must view that evidence in the light most favorable to the appellants, and if the evidence would have permitted a reasonable jury to find in appellants' favor, then the directed verdict on the issue was improper. *Hohmann* v. *Packard Instrument Co.*, 471 F.2d 815, 819 (7th Cir. 1973). *See Brady* v. *Southern Railway Co.*, 320 U.S. 476, 479-80 (1943) (standard for directed verdict).

However, even in the light most favorable to appellants, their evidence does not rebut the showing that the TRD was a "device," for their attempted rebuttal is based on an incorrect reading of the Act. First, the fact that the TRD readings were not the *sole* basis for diagnosis or treatment does not mean that the TRD was not intended for use in the diagnosis and treatment of disease. Even if used in conjunction with other techniques, the TRD was still intended to be a basis for diagnosis and treatment. Appellants' interpretation of the term "device" would exclude from the definition instruments used in connection with other procedures or agents. This inter-

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[2] Appellants stipulated that the TRD instructions in the record were accurate. Dr. Toftness described the financial arrangements in his testimony, and defense witness described their use of the TRD in research

pretation would leave precious few medical instruments within the ambit of the Act, for certainly few instruments are used alone in diagnosis or treatment. An instrument "need not be the only agent in an allegedly curative process to be a device within the definition." *United States* v. *Article of Device . . . "Hubbard Electrometer,"* 333 F. Supp. 357, 360 (D.D.C. 1971).

Second, evidence showing that the TRD was used solely for research does not rebut the evidence that the device was intended for use in the treatment and diagnosis of disease. The research in the instant case necessarily involved the use of the TRD for diagnosis and treatment, for it was the effectiveness of the instrument in precisely those uses which was being tested. The research simply could not be carried out without using the TRD in the diagnosis and treatment of disease. The appellants' own evidence regarding effectiveness of the TRD showed that they intended it for use, and in fact used it, in diagnosis and treatment. We cannot disentangle the "research" from the research methods used. Under appellants' theory, a medical device in the research stage of development could be completely exempt from the Act's regulatory provisions even when the device was being used in the clinical diagnosis and treatment of patients for research purposes. But the Act and its regulations do not except instruments involved in research from the definition of "device," for those instruments may also pose a threat to public health in the research stage. Instead, special, less restrictive labeling requirements apply to investigational devices. *See* 21 U.S.C. § 360j(g) (exemption for devices for investigational use); 21 C.F.R. §§ 812.1 -- .150 (1983) (regulations for investigational use of devices); 21 C.F.R. § 801.122 (1983) (exemption for research "not involving clinical use"); H.R. Conf. R. 1090, 94th Cong. 2d Sess. 64, *reprinted* in 1976 U.S. Code Cong. & Ad. News 1116-17.

We recognize that the appellants were obliged to come forward with evidence of the TRD's effectiveness, and such proof ordinarily involves research into the effectiveness of the device in its intended clinical uses. However, appellants were not placed in a Catch-22. It is possible first to investigate an instrument in a way which will not be subject to the full panoply of labeling requirements for devices on the open market, and then to use the results of the investigation to meet the law's requirements for devices on the market. *See* 21 C.F.R. §§ 801.122 and 812.1 — .150 (1983). Appellants have not argued that the TRD falls within an exception for investigational devices.

Because the government introduced substantial and convincing evidence showing that the TRD was intended for use in the diagnosis and treatment of disease, and because the appellants' evidence did not, under the structure of the Act, rebut that showing, the district court correctly instructed the jury that the TRD was a "device" within the meaning of 21 U.S.C. § 321(h). A reasonable jury could not have found otherwise.

III

We next address the burden of proof on the misbranding of prescription devices. To reach this issue, we must follow an elaborate trail through both the United States Code and the Code of Federal Regulations. We begin our trek with section 304(a)(1) of the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 334(a)(1), which provides for the seizure and condemnation of articles of drug or device which are "adulterated or misbranded" in interstate commerce. The parties stipulated that the TRD has moved in interstate commerce, and we have shown in Part II that the TRD is a "device." To learn whether the TRD is "misbranded," we turn to section 502 of the Act which provides in relevant part:

> A drug or device shall be deemed to be misbranded—
>
> ***
>
> (f) Unless its labeling bears (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of user: *Provided,* that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 U.S.C. § 352(f). In this case the government has argued that the TRD did not bear "adequate directions for use" as required in section 502(f)(1). For a definition of "adequate directions for use," we leave the United States Code behind and journey into the Code of Federal Regulations. In the section dealing with medical devices, we read that: " 'Adequate directions for use' means directions under which the layman can use a device safely and for the purposes for which it is intended." 21 C.F.R. § 801.5 (1983). Obviously there are many medical devices which would be ineffective at best, and dangerous at worst, if left in the hands of a layman, and section 801.5 appears to deem any such devices "misbranded" and thus subject to seizure. However, the regulations provide several exemptions from the "adequate directions for use" requirement. *See* 21 C.F.R. §§ 801.109 — .127 (1983). The broadest of these exemptions, and the one at issue in this case, is the exemption for "prescription devices," that is, those devices which require the supervision of a licensed practitioner for their safe and effective use. 21 C.F.R. § 801.109 (1983).

In this case the parties have stipulated that the TRD cannot be used by laymen; therefore, it would be impossible for the TRD to be labeled with "adequate directions for use" as defined in 21 C.F.R. § 801.5. Under the statute and regulations, the device is thus misbranded unless it falls within one of the exemptions from the requirement, and the appellants in this case have always contended that the TRD falls within the "prescription device" exemption in 21 C.F.R. § 801.109.

In examining section 801.109 of the regulations, we note that the device must meet each of the conditions set forth in the section. The issue here centers upon subsection (c) of the regulation, which requires that:

> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, any precautions *under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: Provided, however,* that such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

21 C.F.R. § 801.109(c) (1983) (emphasis supplied). The consequence of the italicized language is that a prescription device is misbranded unless it can be used safely and effectively for the purposes for which it is intended. That

is, the device has to work — if it does not work, it is misbranded. And the main issue at trial here was whether the TRD in fact works. The government introduced evidence to prove it does not, and the appellants introduced evidence to show it does. The district court instructed the jury that appellants had the burden of proving that the TRD works, and the main issue on appeal is whether this instruction was proper.

The appellants contend that the government should have had the burden of proving that the prescription device exemption did not apply because the government generally has the burden of proving misbranding. *See United States* v. *Four Cases . . . Slim-Mint Chewing Gum,* 300 F. 2d 144, 148 (7th Cir. 1962). The government responds with the general principle that a party claiming entitlement to a statutory exemption bears the burden of proving the entitlement. *United States* v. *First City National Bank,* 386 U.S. 361, 366 (1967); *Federal Trade Commission* v. *Morton Salt Co.,* 334 U.S. 37, 44-45 (1948).[3] Apart from these two general principles and the structure of the statute and regulations, there is very little to guide our consideration of this issue. The statute and regulations are silent, and there appear to be no indications in the history of the legislation or the regulations which could assist us. The parties have cited a number of cases

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[3] The courts have applied this general principle to actions under the Food, Drug, and Cosmetic Act. *See, e.g., Durovic* v. *Richardson,* 479 F.2d 242, 250 n.6 (7th Cir.) (exemption for drugs generally recognized as safe and effective), *cert. denied,* 414 U.S. 944 (1973); *United States* v. *An Article of Drug . . . "Bentex Ulcerine,"* 469 F.2d 875, 878 (5th Cir. 1972) (burden on claimant to prove drug is entitled to exemption, *cert. denied,* 412 U.S. 938 (1973).

to us, but only three address this issue even tangentially, and they are inconclusive.[4]

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[4] Appellants rely most heavily on *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981), but that case does not support their position. In *Evers* there was no dispute at all over the burden of proof: the facts were undisputed and the case was decided on summary judgment. The case addressed only the application of 21 U.S.C. § 331(k) to the unusual situation in which a physician held a prescription drug for sale only to his patients—not to any other physicians. The court held that the law could not "reasonably be read to require a physician who is holding a drug for sale only to patients to provide adequate information to physicians to whom he is not distributing the drug." 643 F.2d at 1053. The appellants here emphasize the court's statement:

> Since Calcium EDTA is a prescription drug, the FDA can establish an act of misbranding under section 502(f)(1) of the Act only by proving that Dr. Evers did not provide adequate information for use by physicians, as is required by the exceptions to that section.

643 F.2d at 1052. The quoted sentence appears to assume that the FDA bears the burden of proof with regard to any exceptions to the misbranding rules. But as we have noted, there was no factual dispute in *Evers*, and the court did not consider the burden of proof issue apart from that passing comment. Therefore, we do not think *Evers* is dispositive on this issue.

The government in turn relies most heavily on *United States* v. *Articles of Device Consisting of Three Devices . . . "Diapulse,"* 527 F.2d 1008 (6th Cir. 1976) (*"Diapulse"*). At issue in *Diapulse* was the application of the prescription device exemption to the labeling requirements. The claimants argued that the device fell within the proviso that labeling need not contain certain information which is "commonly known to practitioners licensed by law to use the device." 21 C.F.R. § 1.106(d)(3) (1976) (predecessors to current 21 C.F.R. § 801.109(c) (1983)). The government had presented affidavits from physicians saying the relevant information was not commonly known, and the claimant presented no evidence on the issue. The court of appeals therefore held that the government was entitled to summary judgment. In a footnote, the court

(footnote continued)

Our only significant guides, therefore, are the structure of the statute and regulations, and the two general rules already noted. We agree with appellants that the government generally bears the burden of proving misbranding. But as the statute and regulations are structured, the government met its burden by proving that the TRD (1) was a "device" under the Act; (2) moved in interstate commerce, and (3) did not bear directions for use adequate to permit a layman to use it safely and effectively. The fact that the government got a directed verdict on the first issue and that the parties stipulated to the second and third does not affect the burden of proof. Under the logic of the statute and regulations, we are persuaded that the prescription device provisions of 21 C.F.R. § 801.109

(footnote continued)

said it believed that the claimant had the burden of proving the elements of the exception for commonly known information and that in the absence of any evidence from the claimant, the government should prevail. 527 at 1012 n.6. However, the footnote in *Diapulse* dealt with an exception within an exception, thus making more clearly applicable the principle that the burden of proof is on the party claiming entitlement to a statutory exception. In addition, the footnote was dictum, for the court decided the case based on the claimant's failure to rebut the government's affidavits.

The Fifth Circuit approved a parallel regulatory structure for prescription drugs in *United States* v. *Articles of Drug*, 625 F.2d 665 (5th Cir. 1980). There the district court had found the "layman" standard for adequate directions for use to be unreasonable as applied to prescription drugs. The Fifth Circuit reversed and held that the regulatory scheme employing the general "layman" standard in conjunction with exemptions for prescription drugs was a reasonable interpretation of the Act and of Congress' purpose. 625 F.2d at 674-75. The court in *Articles of Drug* did not expressly consider the burden of proof issue, but it did approve a parallel regulatory structure with a general rule and exemptions which appear to impose on proponents of prescription drugs the burden of proving that an exemption applies.

are framed as an exemption from the more general labeling requirements.

In accordance with our analysis, a device is "misbranded" unless it bears "adequate directions for use." 21 U.S.C. § 352(f)(1). The regulations define "adequate directions for use" as directions appropriate for a layman. 21 C.F.R. § 801.5. Then, Subpart D of the labeling regulations establishes various exemptions from the general labeling requirements, including the prescription device exemption. 21 C.F.R. §801.109. The FDA has framed the prescription device labeling requirement as an exemption, and appellants claim they qualify under it. Thus, appellants would appear to bear the burden of proof under the reasoning of *United States* v. *First City National Bank, supra,* 386 U.S. at 366, unless placing the burden of proof on them would be contrary to the Act.

Appellants tell us that it would be absurd to treat the prescription device exemption as a true exemption, for it makes no sense to suggest that sophisticated medical devices — which cannot be used by laymen — are presumptively misbranded merely because they do not include directions for laymen. Certainly the FDA could have promulgated regulations which would have established two categories of devices — prescription and over-the-counter — with two separate sets of labeling requirements. In proceeding against a device under such regulations, the FDA would presumably choose whether to proceed under either the prescription or the over-the-counter provisions of the regulations. Under such a hypothetical regulatory scheme, we would have little difficulty in holding that the government bore the burden of proving that the device did not satisfy the prescription device requirements. But that scheme is, of course, hypothetical. Instead, the FDA promulgated the regulations actually before us, and those

regulations make prescription devices one of several exemptions to the more general labeling requirements. No purpose justifying this old structure occurs to us other than the purpose of shifting the burden of proof. By treating the large category of prescription devices under an exemption to the more general requirements, the FDA appears to have wanted to make its task somewhat easier by placing on claimants the burden of proving that their device is safe and is actually effective for its intended purposes.

Although this regulatory arrangement may seem strange insofar as it makes prescription devices presumptively misbranded, the device is not contrary to either the letter or intent of the statute. *See United States* v. *Articles of Drug,* 625 F.2d 665, 674-75 (5th Cir. 1980) (exemption for prescription drugs). The exemption framework requires the makers of prescription devices to be able to prove that their devices do in fact work safely for their intended purposes when they are put on the market.[5]

The government also argues that it was appropriate to cast the burden of proof on the appellants because "the information pertinent to an exemption is often peculiarly within the knowledge of the defendant." Brief for the United States at 22. We agree that in cases such as the one before us, the government may be at something of a disadvantage in its access to proof of the degree of effectiveness of the device. For example, in this case several government experts testified that, in their opinion, the

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[5] By way of comparison, before a "new drug" goes on the market, the drug's proponent must submit to the FDA, among other information, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use. . . ." 21 U.S.C. § 355(b)(1).

TRD was completely worthless in diagnosis. The appellants attacked that testimony on the basis that the government's experts had never received the special training at the Toftness School which appellants contend is necessary for the proper use of the TRD. Where the government's access to the necessary information may be limited, as it was in this case, it seems not inappropriate to put the burden of persuasion on the party who claims that the device works and who presumably has better access to the relevant information. The appellants must do more than merely show the government is wrong; it is not unfair that they be expected to come forward with affirmative evidence showing that the device is effective and to bear the burden of persuasion.

Because the appellants are claiming the application of an exemption to the general labeling requirements, and because they appear to be in the better position to come forward with evidence that the TRD works safely and effectively, we conclude that the district court properly instructed the jury that claimants had the burden of proving that the prescription device exemption applied to the TRD.

IV

Finally, appellants contend that the district court erred when it instructed the jury not to "pile an inference on an inference." Appellants say their proof that the TRD worked was necessarily circumstantial, requiring the jury to draw inferences from the evidence presented and then to draw the further reasonable inference that the TRD was effective. According to appellants, the "inference on inference" instruction unduly confined the jury's consideration of the evidence.

Jury instructions which tell the jury not to "pyramid" inferences or pile them on top of one another have long been controversial. *See* 1A J. Wigmore, Evidence § 41

(Tillers rev. 1983). The "inference on inference" instruction cannot be taken literally, for the reasoning process normally begins with known facts which form the basis for inferred facts from which further inferences can be drawn. *See id.* § 41 at 1111. So long as the finder of fact is reasonable to use that inference as the basis for further reasoning. *See Fenner* v. *General Motors Corp.*, 657 F.2d 647, 650-51 (5th Cir. 1981), *cert. denied*, 455 U.S. 942 (1982); *Prudential Insurance Co.* v. *Glasgow*, 208 F.2d 908, 912 (2d Cir. 1953). Nevertheless, the process of inferential or circumstantial reasoning can, in some cases, reach far beyond the reasonable scope of the evidence, arriving at conclusions based more upon speculation or conjecture than upon the evidence at trial. *See Daniels* v. *Twin Oaks Nursing Home*, 692 F.2d 1321, 1324-26 (11th Cir. 1982). For that reason it is entirely appropriate for the trial judge to warn the jury not to get carried away in long, speculative chains of inferences.

In our view the "inference on inference" instruction is clumsy and unnecessarily controversial. As Judge Wisdom wrote:

> The so-called rule against pyramiding inferences, if there really is such a "rule" and if it is anything more than an empty pejorative, is simply legalese fustian to cover a clumsy exclusion of evidence having little or no probative value.

N.L.R.B. v. *Camco, Inc.*, 340 F.2d 803, 811 (5th Cir. 1965). However, the instruction given in this case, when read in context with the other instructions, appears to have been a rhetorical device aimed more against guesswork and speculation than against the normal process of

inferential reasoning.[6] The instruction should not have prevented the jury from engaging in a normal process of reasoning from proven facts to an inference and from there to a further *reasonable* inference.

We deal here with matters of common sense. It is always possible for lawyers, judges or logicians to examine what appears to be a reasonable inference and to show how that inference is actually the sum of several shorter inferential steps. *See, e.g.*, 1 Weinstein's Evidence ¶ 401[09] (1983) (describing inferential steps in several examples). The district court's language, if read strictly

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[6] The relevant portion of the instructions reads as follows:

> Before a fact sought to be established can be said to have been proved by circumstantial evidence alone, it is necessary not only that the circumstances proved by the evidence shall give rise to a reasonable inference of such fact, but also that no other inconsistent equally reasonable inference can be drawn from those same circumstances.
>
> A "reasonable inference" is defined as a process of reasoning whereby from the facts otherwise admitted or established by the evidence in light of your common knowledge and experience, a reasonable and logical conclusion may be drawn that a certain fact is true. A reasonable inference is therefore said to be clearly distinguished from a mere guess or conjecture.
>
> The law does not permit speculation; moreover, on the basis solely of one inference so drawn, a further inference may not be drawn. In other words, you can't pile an inference on an inference, but you may draw an inference only from the facts or circumstances which you find have been established by a preponderance of the evidence.

Tr. at 1010-11. The district judge who presided in this case denied a motion for a new trial based in part on a similar instruction in *Juneau Square Corp. v. First Wisconsin Nat'l Bank*, 475 F. Supp. 451, 460 (E.D. Wis. 1979), *aff'd*, 624 F.2d 798 (7th Cir.), *cert. denied*, 449 U.S. 1013 (1980). There he explained:

> Taken in context, this instruction was not erroneous. It explained to the jury the distinction between reasonable inferences and mere speculation and correctly stated that inferences must be drawn from a factual basis.

475 F.Supp. at 460.

and without regard for the context, could be construed to prohibit any steps except those which cannot be broken down any further. Such a reading, however, would ignore common sense. As an example of the kind of reasoning which appellants contend the instruction might have interfered with, appellants point to their evidence showing high statistical correlations between diagnoses based on the TRD and those based on more familiar chiropractic techniques. The appellants asked the jury to infer from those correlations that the TRD, when used properly, produced findings similar to those of proven techniques. The appellants then asked the jury to reach the further inference that the TRD did in fact work. Such a conclusion would not be speculative, even if we can with hindsight break the process down into two or more steps. We do not believe that the jury would have understood the "inference upon inference" instruction to prohibit them from taking any logical step which might be broken down into two or more smaller steps. Such an interpretation would be contrary to common understanding and inconsistent with the remainder of the district court's instructions. We think it would be the better practice to avoid the "inference on inference" language and to concentrate instead on the jury's duty not to engage in speculation that is beyond the scope of the evidence. However, we find no error here in light of the district court's other language on guesswork and speculation.

For the foregoing reasons the judgment of the district court is

AFFIRMED.

A true Copy:
Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

Case No. 75-C-478 & 75-C-479 (W.D.)

UNITED STATES OF AMERICA,

Plaintiff,

vs.

". . . TOFTNESS RADIATION DETECTOR . . ." et al.,

Defendants.

DECISION AND ORDER

On January 18, 1982, the Court entered judgment pursuant to the jury's verdict in favor of the Government in the above-captioned case. Defendants have moved for a new trial, asserting essentially five grounds in support of their motion. Defendants contend: (1) the Court erred by shifting the burden of proof from the Government to the defendants; (2) the Court erred in finding, as a matter of law, that the Toftness Radiation Detector (TRD) is a "device" within the meaning of 21 U.S.C. § 321(h); (3) the Court erred in admitting into evidence Government Exhibit 24; (4) the Court erred in instructing the jury concerning the use of inferences; and (5) the great weight of the credible evidence favored defendants. For the reasons stated below, defendants' motion for a new trial will be denied.

I. THE BURDEN OF PROOF

In this action, the Government seeks the condemnation of the TRD on the ground it is "misbranded" within the meaning of the Federal Food, Drugs, and Cosmetics Act, 21 U.S.C. § 301 *et seq.* because it fails to provide "adequate directions for use." *See* 21 U.S.C. § 352 (f)(1). The phrase "adequate directions for use" has not been defined by Congress, but the implementing regulations promulgated by the Food and Drug Administration (FDA) explain the phrase to mean directions which could be understood for a layman to use a device or drug safely and for its intended purpose. *See* 21 C.F.R. § 201.5. This interpretation by the FDA has been upheld on a number of occasions. *See, e.g., United States* v. *Colohan,* 635 F.2d 564 (6th Cir. 2980); *United States* v. *Articles of Drug,* 625 F.2d 665 (5th Cir. 1980). In the case of prescription drugs (or, as here, devices), courts have held that, because such drugs, by definition, can be used only under a physician's supervision, they must qualify for a regulatory exemption created by the FDA pursuant to the authority of 21 U.S.C. § 352(f). *See United States* v. *Articles of Drug, supra,* 625 F.2d at 673.

In the context of a device intended solely for use by a licensed practitioner (the situation in the case at bar), the district court, in *United States* v. *Articles of Device [Acuflex; Pro-med]*, 426 F. Supp. 366 (W.D. Pa. 1976), explained the scheme of the FDA regulations as follows:

> The mere fact that the devices were intended to be sold only to licensed operators for use in their practices does not in itself exempt the devices from the requirement that the labeling include adequate directions for use by the laity. *United States* v. *Article of Device* . . .

> *Cameron Spitler, supra; United States* v. *Articles of Drug . . . Alberty Instant Food, supra.* See 38 Fed. Reg. 6419. However, recognizing the value to medical practice and research of devices which cannot be safely used by laymen and for which adequate directions for use therefore cannot be written, Congress has authorized the promulgation of regulations for exemption from § 352(f)(1). Pursuant to this authority, the FDA has promulgated regulations which exempt a device from the labeling requirement of adequate directions for use if: [whereupon the court quoted 21 C.F.R. § 801.109]

426 F. Supp. at 369.

The only regulatory exemption relevant to the instant case is that contained in 21 C.F.R. §801.109 for prescription devices. One of the requirements of the exemption is that any labeling accompanying the device contain "adequate information for . . . use . . . under which practitioners licensed by law to employ the device can use the device safely and for the purpose for which it is intended. . . ." 21 C.F.R. § 801.109(d). The practical import of this requirement is that a device cannot qualify for the exemption if it does not work.

At the close of evidence in the instant case, the Court instructed the jury as follows:

> To prove that the Toftness Radiation Detectors are technically "misbranded" within the meaning of the statute, the government must establish that the seized articles:
>
> 1. are devices;
> 2. were shipped in interstate commerce; and
> 3. do not bear adequate directions for use by laymen.
>
> Although these three elements are those for which the government bears the burden of proof, you need

not concern yourselves with whether they have been established. The Court has ruled that these have been established as a matter of law. You need only concern yourselves with the issue upon which the claimants have the burden of proof.

Because the elements of the government's case are established as a matter of law, you must find that the Toftness Radiation Devices are "misbranded" within the meaning of the statute unless the claimants show that the articles qualify for one of the exemptions from the requirement of bearing adequate directions for use established in the FDA regulations. The claimants bear the burden of proof on the issue of whether the articles qualify for an exemption.

Jury Instructions, p. 8. *See* 21 U.S.C. § 352. Concerning the exemption for prescription devices, the Court instructed the jury:

The Food and Drug Administration was authorized by Congress to promulgate regulations exempting certain devices from "adequate directions for use" requirement, and the Food and Drug Administration has issued such regulations.

The exempting regulations specify the conditions that must be met in order to legally market a device that otherwise would be "misbranded" under the statute. To qualify for any of the exemptions, claimants must prove every fact required to invoke the exemption. Compliance with the conditions in the exempting regulations is mandatory; failure to comply renders the devices ineligible for the exemption and therefore misbranded.

* * *

The FDA regulations specify several conditions which must be met for a device to be considered a prescription device and thereby exempt from the requirement of bearing adequate directions for use. The

only part of the regulation in dispute in this case is paragraph (d), which provides:

> (d) Any labeling . . . that furnishes or purports to furnish information for use of the device [must contain] adequate information for such use, . . . under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. . . .

Jury Instructions, pp. 8-9. *See* 21 C.F.R. § 801.109. The Court concluded the substantive part of its instructions to the jury by summarizing the issue presented as follows:

> The central issue of this case which you must decide is whether the Toftness Radiation Detector is effective for the purposes for which it is intended or, in other words, whether it works. If you find that the Toftness Radiation Detector is effective, then you must find in favor of the claimants. If you find that the Toftness Radiation Detector is not effective, then you must find in favor of the Government. You are reminded that the claimants have the burden of proof on the issue of whether the Toftness Radiation Detector is effective for its intended purpose.

Jury Instructions, p. 10.

Defendants argue that the Court erred in placing the burden of proof concerning exemption from the "adequate directions for use" requirement on them.[1] In sup-

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[1] Defendants' counsel has submitted an affidavit in which he states that after the trial, several members of the jury indicated to him that if the Government had had the burden to prove the TRD does not work, the result of the case probably would have been different. The Court views counsel's assertion as irrelevant since the burden of proof properly was placed on defendants. In any event, the type of evidence which counsel attempts to set forth by way of his affidavit is not a proper subject of inquiry. *See McDonald* v. *Pless*, 238 U.S. 264 (1915).

port of their argument, they cite a number of cases which indicate that as a general matter, the burden of proving "misbranding" is on the Government. *See United States* v. *4 cases * * * Slim-Mint Chewing Gum*, 300 F.2d 144, 148 (7th Cir. 1962); *United States* v. *Articles of Drug Labeled Colchicine*, 442 F. Supp. 1236, 1241 (S.D. N.Y. 1978); *AMP, Inc.* v. *Gardner*, 275 F. Supp. 410, 412 (S.D. N.Y. 1967), *aff'd*, 389 F.2d 825 (1d Cir. 1969); *United States* v. *60 28-Capsule Bottles*, 211 F. Supp. 207, 214 (D.N.J. 1962), *aff'd*, 325 F.2d 513 (3d Cir. 1963). None of these cases, however, nor any of the other cases cited by the parties, directly address the issue presented here, *i.e.*, who bears the burden of proving qualification for the prescription device exemption from the "adequate directions for use" requirement.[2]

As a general rule of statutory construction, however, the party claiming an exemption under a special exception to a statute bears the burden of proving exemption. *FTC* v. *Morton Salt Co.*, 334 U.S. 37, 44-45 (1948). *See also United States* v. *First City National Bank of Houston*, 386 U.S. 361, 366 (1967); *Rheem Mfg. Co.* v. *Rheem*, 295 F. 2d 473, 475 (9th Cir. 1961); *Detroit Edison Co.* v. *SEC*, 119 F.2d 730, 739 (6th Cir.), *cert. denied*, 314 U.S. 618 (1941). Defendants argue that this general rule has no application here because there is no statutory requirement that prescription devices have adequate directions for lay use. There is, however, a regulatory scheme which requires devices to bear adequate directions for lay use, unless some

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[2] Defendants discuss at length the Fifth Circuit's decision in *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981), contending that it supports their argument concerning the burden of proof. *Evers*, however, is distinguishable. There, the Court concluded that the defendant did not violate the misbranding prohibition of the Federal Food, Drugs, and Cosmetics Act because he was administering the drug to his own patients and not distributing it to other physicians.

exemption applies. As noted by the Sixth Circuit in *Colahan, supra,* "Implementation of the Act's complex statutory scheme is a job entrusted in the first instance to the FDA." 635 F.2d at 567. The regulatory scheme adopted by the FDA is longstanding and thus "entitled to great respect." *Id.* at 568 (citing *Board of Governors* v. *First Lincolnwood Corp.,* 439 U.S. 234, 238 (1978)). Hence, in the Court's view, the fact that the exemption at issue here appears in the FDA's implementing regulations as opposed to the Act itself is not a sound basis for ignoring the general rule.

Moreover, in a context analogous to the present case, the Sixth Circuit, in *United States* v. *Articles of Device . . . "Diapulse",* 527 F.2d 1008 (6th Cir. 1976), concluded that the claimant had the burden of proving the devices at issue were exempt from the "adequate directions for use" requirement. In *Diapulse,* the claimant admitted that the devices did not bear adequate directions for use within the meaning of 21 U.S.C. § 352(f)(1). Nonetheless, the claimant alleged that the devices were exempt from the labeling requirements because directions for use of the devices were "commonly known to practitioners licensed by law to use the device." 21 C.F.R. § 1.106(d). In reversing the district court's decision and remanding the case for entry of summary judgment in favor of the Government, the court stated: "We believe that claimant had the burden of proving that the devices were exempt from the labeling requirement by showing that directions for their use were commonly known by practitioners licensed to use the devices." 527 F.2d at 1012 n. 6. Although defendants in the case at bar argue at length that *Diapulse* is distinguishable, the Court concludes that it is sufficiently analogous to support the Court's instructions concerning the burden of proof.

Therefore, for the reasons stated above, the Court concludes it did not commit error in instructing the jury concerning the burden of proof.[3]

II. THE TRD AS A "DEVICE"

As indicated in the instructions to the jury, quoted above, the Court concluded at the close of evidence that the issue of whether the TRD was a "device" within the meaning of the Federal Food, Drugs, and Cosmetics Act was established as a matter of law by the evidence presented. The Court, accordingly, instructed the jury that it need not consider the issue. Jury Instructions, p. 8. Defendants argue that the Court erred in finding the TRD to be a "device" as a matter of law.

An instrument is a "device" under the meaning of the Act if it is "intended for use in the diagnosis or treatment of disease or other conditions . . . in man." 21 U.S.C §321(h). Thus, the test for determining whether an article is a device is whether it is intended for use in diagnosis or treatment. Defendants argue that there was substantial credible evidence presented to support their theory that the intended use of the TRD was research, rather than diagnosis or treatment. They contend, therefore, that the issue of TRD's status as a device should have been submitted to the jury.

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[3] Defendants also argue that their rights to due process under the Fifth Amendment and to a jury trial under the Seventh Amendment were violated by reason of the instructions concerning the burden of proof. This argument lacks merit. As the district court noted in *United States* v. *Naples*, 192 F. Supp. 23 (D.D.C. 1961), "[t]here is no question that it is within the purview of the legislative branch of the Government to regulate the burden of proof, and that it is not violative of due process of law to cast on the defendant the burden of proof. . . ." *Id.* at 39 (citing *Leland* v. *Oregon*, 343 U.S. 790 (1951)), *rev'd on other grounds*, 307 F.2d 618 (D.C. Cir. 1962).

The Court cannot agree. The "intended use" of a product within the meaning of the Act is determined from the various circumstances surrounding its distribution. *Cf. Hanson* v. *United States*, 417 F. Supp. 30, 35 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976). In the instant case there was overwhelming evidence presented which showed that the TRD was intended to be used in the diagnostic treatment of patients, and that it was so used in the diagnostic process with patients. *Cf. United States* v. *Article of Device . . . Hubbard Electrometer*, 333 F. Supp. 357, 360 (D.D.C. 1971). In particular, the financial circumstances surrounding the distribution of the TRD strongly indicated that its intended use was diagnostic, rather than research-oriented. The evidence presented, even when viewed in a light most favorable to the defendants, was such that no reasonable person in a fair and impartial exercise of his judgment could have reached a different conclusion. *See Hohmann* v. *Packard Instrument, Inc.*, 471 F.2d 815, 819 (7th Cir. 1973). Thus, the Court concludes it did not err in withholding from the jury's consideration the issue of whether the TRD is a "device" under the meaning of the Act.

III. GOVERNMENT EXHIBIT 24

Defendants argue that the Court committed reversible error by admitting into evidence Government Exhibit 24 (GX24), a letter, dated October 9, 1975, from Dr. R.W. Van Krevelen to Dr. Toftness. Dr. Van Krevelen, a chiropractor, testified at trial on behalf of the Government concerning his opinions about the validity of the TRD. He testified that he did not believe the TRD worked as claimed by the defendants. On cross-examination, defendants' counsel questioned him regarding the subject-matter of GX24 without attempting to introduce the letter into evidence. On redirect, Government counsel attempted to

clarify the matters addressed during cross-examination by offering the letter into evidence. After a side-bar conference during which defendants' counsel objected to the admission of the letter on the ground of undue prejudice, the Court admitted GX24 into evidence. Defendants' counsel then moved for a mistrial on the ground that certain statements in the letter were unduly prejudicial to defendants' case. The Court denied the motion and instead issued an appropriate cautionary instruction.

Defendants now move for a new trial, again on the ground that certain statements contained in GX24 unduly prejudiced defendants' case. The Court has reexamined GX24 and concludes that any prejudice which may have been caused by the statements in the letter was adequately addressed by the cautionary instruction given by the Court. Moreover, aside from the cautionary instruction, the statements which defendants find so objectionable were not, in the Court's view, so closely related to the central issue in the case as to affect the substantial rights of the parties. *See* Fed.R.Civ.P. 61. Accordingly, the Court concludes it did not commit prejudicial error by admitting GX24 into evidence.

IV. INFERENCE INSTRUCTION

Defendants assert that the Court committed prejudicial error by giving the standard jury instruction which prohibits the piling of one inference upon another. *See* Jury Instructions, p. 4. In support of the argument, defendants cite the Seventh Circuit's decision in *Ross* v. *Ruan Transport Corp.*, 214 F.2d 583 (7th Cir. 1954). But *Ross* lends no support for defendants' argument. The court of appeals simply held that there was no piling of inferences with regard to the evidence presented at trial and the conclusions reached. *Id.* at 585. Defendants also cite 1 *Wigmore on Evidence* (3d Ed.), § 41 at 434, in which it is

argued that the prohibition against piling inferences is invalid. Yet, as pointed out by the Government, Wigmore specifically notes that various courts have approved the inference-piling prohibition. *See e.g., Standard Accident Insurance Co.* v. *Nicholas,* 146 F.2d 376, 378 (5th Cir. 1944); *Westland Oil Co.* v. *Firestone Tire & Rubber Co.,* 143 F.2d 326, 330 (8th Cir. 1944). Thus, the Court has serious doubt concerning whether it was error to give the instruction.

In any event, the Court has little trouble in holding that, even if the instruction was erroneous, the error was harmless because it did not affect the substantial rights of the parties. Fed.R.Civ.P. 61.

V. WEIGHT OF THE EVIDENCE

As their final argument, defendants argue that a new trial should be granted in the interest of justice and because the jury's verdict was against the great weight of the evidence.

The standard for a motion for a new trial based on the weight of the evidence was stated by the Seventh Circuit in *Continental Air Lines, Inc.* v. *Wagner-Morehouse, Inc.,* 401 F.2d 23 (7th Cir. 1968):

> If the evidence in the record, viewed from the standpoint of the successful party, is sufficient to support the jury verdict, a new trial is not warranted merely because the jury could have reached a different result . . . The trial court (may not) substitute its judgment for that of the jury on disputed issues of fact.

Id. at 30. The Court's function in passing on a motion for a new trial is essentially to see that there is no miscarriage of justice. 6A *Moore's Federal Practice* ¶ 59.05.

Applying the foregoing standard to the evidence presented in the instant case, the Court has no reservation in denying the defendants' motion. The Government presented more than ample evidence to demonstrate, as a scientific matter, the invalidity of the TRD. The Court is convinced that there was no miscarriage of justice in the jury's verdict. Therefore, the Court concludes that defendants' assertion concerning the weight of the evidence must be rejected.

SUMMARY

A motion for a new trial is addressed to the sound discretion of the trial court. Wright & Miller, *Federal Practice and Procedure* § 2803. A court should not grant a new trial unless it is reasonably clear that prejudicial error has occurred or that substantial justice has not been done. *Id.* For the reasons indicated above, the Court concludes that there was no prejudicial error and that substantial justice was done.

Therefore, the Court hereby DENIES defendants' motion for a new trial.

SO ORDERED this 18th day of January 1983, at Milwaukee, Wisconsin.

Robert W. Warren
ROBERT W. WARREN
UNITED STATES DISTRICT
JUDGE

Opinion by Judge Cudahy

JUDGMENT — ORAL ARGUMENT

UNTED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604
April 4, 1984

Before

Hon. Richard D. Cudahy, Circuit Judge
Hon. Jesse E. Eschbach, Circuit Judge
Hon. John L. Coffey, Circuit Judge

United States of America, Plaintiff-Appellee,
vs.
No. 83-1404

An Article of Device. . . "Toftness Radiation Detector. . . ," Toftness Post-Graduate School of Chiropractic, Inc., a corporation, and Irwing N. Toftness, an individual, Defendants-Appellants.

Appeal from the United States District Court for the Western District of Wisconsin.

Nos. 75 C 478, 75 C 479

Judge Robert W. Warren

This cause was heard on the record from the United States District Court for the Western District of Wisconsin, and was argued by counsel.

On consideration whereof, IT IS ORDERED AND ADJUDGED by this Court that the judgment of the said District Court in this cause appealed from be, and the same is hereby AFFIRMED, with costs, in accordance with the opinion of this Court filed this date.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

United States of America, Plaintiff,

v.

An article of device . . . "Toftness Radiation Detector," Toftness Post-Graduate School of Chiropractic, Inc., a corporation, and

Irwing N. Toftness, an individual, Defendants.

75-C-478 & 479

JUDGMENT

The jury in this action having returned a general verdict in favor of the plaintiff, the United States of America, it is HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and the parties to the action.

2. The two defendant Toftness Radiation Detectors are in violation of the Food, Drug, and Cosmetic Act, and shall be condemned and forfeited to the United States. The defendant devices shall be released to the Food and Drug Administration, which may use them for educational purposes or dispose of them by destruction or sale (with any proceeds to go to the Treasury of the United States), as that agency sees fit.

3. a. The Toftness Post-Graduate School of Chiropractic, Inc., and Irwing N. Toftness, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, shall be, and hereby are, permanently en-

joined from manufacturing, promoting, selling, leasing, distributing, shipping, delivering, or using in any way any Toftness Radiation Detector. (As used herein, "Toftness Radiation Detector" shall mean any article of device that is in any way labeled or designated as a Toftness Radiation Detector, or any article of device that is substantially the same as, or employs the same basic principles as, the defendant Toftness Radiation Detectors.)

b. The Toftness Post-Graduate School of Chiropractic, Inc., and Irwing N. Toftness shall be, and hereby are, ordered to provide to the Minneapolis District Office of the Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minnesota 55401, within 30 days, a statement listing all persons who have either received training in the use of the Toftness Radiation Detector or are believed by defendants to be in possession of a Toftness Radiation Detector. This statement shall also indicate the number of Toftness Radiation Detectors in the possession of each person, as well as the number in the possession of defendants, and provide a written explanation concerning each person who has received training in the use of the Toftness Radiation Detector but is not believed to be in possession of a Toftness Radiation Detector.

c. The Toftness Post-Graduate School of Chiropractic, Inc., and Irwing N. Toftness shall be, and hereby are, ordered to send a letter approved by the Food and Drug Administration, by certified mail return receipt requested, within 30 days, to every person who is believed to be in possession of a Toftness Radiation Detector. Each letter shall enclose a copy of this judgment, cancel the lease or other agreement by which the person is in possession of the Toftness Radi-

ation Detector, and order the return of the device to defendants. Each person in possession of a Toftness Radiation Detector shall be, and hereby is, ordered to return the device to the Toftness Post-Graduate School of Chiropractic, Inc., within ten days of the receipt of this letter, with defendants to bear the cost of postage or other shipping charges.

d. The Toftness Post-Graduate School of Chiropractic, Inc., and Irwing N. Toftness shall be, and hereby are, ordered to provide to the Minneapolis District Office of the Food and Drug Administration, at least once every 30 days until all Toftness Radiation Detectors have been returned: 1) duplicate copies of all return receipts and correspondence received in response to the letters sent pursuant to paragraph 3(c) above; and 2) a statement indicating the number of Toftness Radiation Detectors in their possession, the names of the persons from whom they were received, and the number received from each person. All Toftness Radiation Detectors shall be kept in a specifically designated place approved by the Food and Drug Administration and the Food and Drug Administration shall be allowed to pick them up at that place between 9:00 a.m. and 5:00 p.m. on any weekday. The Food and Drug Administration may use the Toftness Radiation Detectors for educational purposes or dispose of them by destruction or sale (with any proceeds to go to the Treasury of the United States), as it sees fit.

4. For the purpose of making inspections in-order-to determine that the requirements set forth in the preceding injunction (paragraph 3 of this judgment) have been met and to ensure continuing compliance with the terms of the injunction, duly authorized representatives of the Food and Drug Administration shall be granted free access be-

tween 9:00 a.m. and 5:00 p.m. on any weekday to: (1) defendants' places of business, (2) all Toftness Radiation Detector devices and component parts located therein, and (3) all related labeling, communications, correspondence, doctor or patient lists, complaints, agreements, contracts, leases, records, and other materials. The cost of these inspections and all other activities undertaken by the Food and Drug Administration pursuant to this judgment shall be borne by defendants at the rate of $31.50 per hour and fraction thereof per person for inspectional work and $74.00 per day per person for subsistence expenses, where necessary. Defendants shall also compensate plaintiff for all necessary travel expenses. The inspection authority granted under this judgment is apart from, and in addition to, the authority to make inspections under the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 372 and 374.

5. The United States shall recover from defendants all court costs and fees, as well as storage and other expenses.

6. The jurisdiction of this Court is retained for the purpose of enforcing or modifying this judgment and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate.

SO ORDERED.

/s/ Robert W. Warren
UNITED STATES DISTRICT JUDGE

Dated: January 18, 1982

DISTRICT COURT'S JURY INSTRUCTION PLACING BURDEN OF FROOF ON ISSUE OF MIS-BRANDING ON THE DEFENDANTS (PETITIONERS HERE)

Now, generally in a civil case such as this, the burden of proof is on the plaintiff to establish the elements of its claim by a preponderance of the evidence; nevertheless, as to one of the issues in this case the burden of proof will be on the claimants, or as they have said, called themselves sometimes, the defendants.

You will be instructed in a few moments as to that issue upon which the claimants have the burden of proof. As to that issue the claimants must prove the necessary facts by a preponderance of the evidence in order to prevail in the case.

* * *

In this case, the Government alleged that they seized the Toftness radiation detectors or devices which are misbranded because they do not bear adequate directions for use. The Government alleges that the articles are "misbranded" within the meaning of 21 United States Code, Section 352(f)(1), and that they are not exempt from the requirement of bearing adequate directions for use under FDA regulations.

To prove that the Toftness radiation detectors are technically "misbranded" within the meaning of the statute, the Government must establish that the seized articles, one, are a device; two, were shipped in interstate commerce; and, three, do not bear adequate directions for use by laymen.

Although these three elements are those for which the Government bears the burden of proof, you need not concern yourself with whether they have been established.

The Court has ruled that these have been established as a matter of law.

You need only concern yourself with the issue upon which the claimants have the burden of proof, and I will be explaining that now.

Because the elements of the Government's case are established as a matter of law, you must find that the Toftness radiation devices are misbranded within the meaning of the statute unless the claimant shows that the articles qualify for one of the exemptions from the requirements of bearing adequate directions for use, that are established in the FDA regulations.

The claimants bear the burden of proof on the issue of whether the articles qualify for an exemption.

The Food & Drug Administration was authorized by Congress to promulgate regulations exempting certain devices from the "adequate directions for use requirement," and the Food & Drug Administration has issued such regulations. The exempting regulations specify the conditions that must be met in order to legally market a device that otherwise would be "misbranded" under the statute.

To qualify for any of the exemptions, claimants must prove every fact required to invoke the exemption status. Compliance with the conditions in the exempting regulation is mandatory. Failure to comply renders a device as ineligible for the exemption and therefore "misbranded."

The fact that the Toftness radiation detector is not available to laymen but rather is restricted to use by licensed chiropractors who have received a course of instruction as to its use does not mean that the articles are automatically exempted from the requirement of bearing adequate directions for use.

Prescription devices, that is devices that can only be used under the supervision of a licensed practitioner, comprise a primary category of devices that are exempted from this requirement of bearing adequate directions for use. A chiropractor is a licensed practitioner.

The FDA regulations specify several conditions which must be met for a device to be considered a prescription device, and thereby exempt from the requirement of bearing adequate directions for use. The only part of the regulations in dispute, there are a number of them, but there's only one of them that's in dispute in this case is Paragraph D which provides, and this is a somewhat short statement of that Sub-paragraph D, any labeling that furnishes or purports to furnish information for use of the device must contain adequate information for such use under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented.

In determining whether the written information for use of the instrument, that is the so-called labeling, is adequate, you are entitled to consider the circumstances under which the instrument and written information are distributed.

This includes the fact that distribution is made only to those doctors of chiropractic who have attended the Toftness post-graduate school and have been personally instructed and trained in the use of the instrument.

* * *

The central issue in this case, both counsel have referred to this and I will reiterate this, we go through a lot of explanation to arrive at really what's in this particular instance a rather simple issue before you, not that the issue is simple, I shouldn't say that, but that the de-

cision that you have to make is a straightforward one, and the central issue in this case which you must decide is whether the Toftness radiation detector is effective for the purposes for which it is intended, or, in other words, whether it works.

If you find the Toftness radiation detector is effective, then you must find in favor of the claimant. If you find that the Toftness radiation detector is not effective, then you must find in favor of the Government.

You are reminded that the claimants have the burden of proof on the issue of whether the Toftness radiation detector is effective for its intended purpose.

JURY INSTRUCTION ON "MISBRANDING" BURDEN OF PROOF REQUESTED BY DEFENDANTS (PETITIONERS HERE) WHICH DISTRICT COURT DECLINED TO GIVE.

DEFENDANTS' INSTRUCTION NO. 4

Devices that are only used by or under the supervision of a licensed practitioner are exempt from the requirement of bearing adequate directions for use. Chiropractors are licensed practitioners.

The FDA regulations specify the following conditions which must be met for a device to be considered exempt from the requirement of bearing adequate directions for use:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, . . . shall be exempt from . . . the act if all the following conditions are met:

(a) The device is:

(1) (i) In the possession of a person, or his agents or employees, regularly lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, . . . licensed by law to use or order the use of such device; and

(2) Is to be sold only to . . . such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments bears:

(1) The statement: "Caution: Federal law restricts this device to sale by or on the order of a "chiropractor)", . . . and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device for the purpose for which it is intended, including all purposes for which it is advertised or represented: Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device. . . .

(d) Any labeling, . . . that furnishes or purports to furnish information for use of the device contains adequate information for such use, . . . under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. . . .

> (e) All labeling, . . . bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

In determining whether the written information for use of the instrument (that is, the so-called "labeling") is adequate, you are entitled to consider the circumstances under which the instrument and written information are distributed. This includes the fact that distribution is made only to those doctors of chiropractic who have attended the Toftness Post-Graduate School and have been personally instructed and trained in the use of the instrument.

You should find in favor of the Government only if it has satisfied you by a preponderance of the credible evidence that the defendants have failed to meet all of the exemption requirements just stated to you. If you are not so satisfied, you should find in favor of the defendants.

DISTRICT COURT'S ORAL RULING ON OBJECTIONS OF DEFENDANTS (PETITIONERS HERE) TO JURY INSTRUCTION ON "MISBRANDING" BURDEN OF PROOF

The Court: All right. There being no objections on the Government's part, the Court would just comment on the claimants' other objections.

Really they are part and parcel of one total issue, Defendants 3 and 4, which were not given were discussed at great length in the instruction conference, as was discussed at great length the question of who bore the burden of proof, and the burden of moving forward in the case. And really the objections on Page 3, Page 8 and Page 10 which have been enunciated by the Defendant are all part and parcel of the same issue, namely, the burden of proof.

It was the Court's view that under the statute an article has been misbranded when it's established that the articles are devices that were shipped in interstate commerce and did not bear adequate directions for use by laymen. Under the facts in this case there really were no issues on those three points, and the Court ruled that they had been established as a matter of law. That being the situation, then there would have been a victory for the Government save that the real issue in this case dealt with the question of, as I have indicated to the instructions, whether or not when you have this kind of a advice it was intended specifically for professionals.

The claimants could qualify for the exception that was intended to cover that category of individuals, and in other words, it took on the nature of an affirmative defense, and the normal parlance of the law on affirmative defense, the one raising that has the burden of proof, so that the Court's view of this rather unusual case is that the Government had the burden of proof on the case in chief, but none of the elements of that case in chief were in controversy and were all established or stipulated. One of the two, beyond any shadow of doubt.

That being the situation, the real issue, whether the device worked or not determined whether or not the exemption was applicable under Sub-section D of 352(f)(1), and the Court is satisfied that it was correct in laying the burden of proof on the claimants in that regard, so that I see no reason to change my position.

We adequately ventilated the matter in chambers and although that's not all on the record both counsel, in the event that you talk to the gentlemen down in Chicago in the Seventh Circuit, you know what the positions are and you can be arguing that as you address yourself to their wisdom.

On the inference on the inference, the Court again is satisfied that's a standard instruction from Devitt and Blackmar that''s contrary to what counsel contends. I think that there is ample precedent for the view that you cannot establish or draw an inference from an inference, so the Court will let that instruction stand.

Mr. Kersten: Your Honor, without expanding the text that I'm objecting to, I would like to add a grounds on my objections to the instructions appearing on Page 8 and 9. In addition to the shifting of the burden of proof which I have already spoken to, I would like to add that I feel the numerous references in the instruction to misbranding in the context of the case and in connection with these supposed lack of the instrument being accompanied by adequate directions for use by a layman has a tendency to prejudice the jury. In other words, we are going in with the instrument already being labeled in effect misbranded by the Court's instructions, and having then to sort of undo that unfortunate Imprimatur by proving that it were exempt.

Our position would be that we are not misbranded at all having in mind this is an instrument for use by professionals unless and until it is established by the Government that we have, in the context of the facts here, unless and until it's established by the Government that the instrument is useless and therefore cannot have appropriate information supplied with it.

The Court: Normally I would be agreeing with you, counselor, but this is such a strange statute, and the way it's worded is so different from that to which we are usually dealing that I am satisfied that we treated it the right way.

All right, gentlemen.

No. 84-162

In the Supreme Court of the United States

OCTOBER TERM, 1984

AN ARTICLE OF DEVICE: "TOFTNESS RADIATION DETECTOR," ET AL., PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

REX E. LEE
Solicitor General
Department of Justice
Washington, D.C. 20530
(202) 633-2217

TABLE OF AUTHORITIES

In the Supreme Court of the United States

OCTOBER TERM, 1984

No. 84-162

AN ARTICLE OF DEVICE: "TOFTNESS RADIATION DETECTOR," ET AL., PETITIONER

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UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

In this misbranding case under the Federal Food, Drug, and Cosmetic Act, petitioners challenge the ruling of the courts below that a party claiming entitlement to the prescription device exemption has the burden of proving all elements of the exemption, including the effectiveness of the device.

1. The Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 301 *et seq.*, authorizes the United States to seize and condemn misbranded medical devices. 21 U.S.C. 321(h), 334(a). A device is "misbranded" unless its labeling bears "adequate directions for use." 21 U.S.C. 352(f). The Act authorizes

the Secretary of Health and Human Services to promulgate regulations defining exemptions from the misbranding provision (*ibid.*) and otherwise providing for efficient enforcement of the Act. 21 U.S.C. 371(a).

The Secretary's regulations interpret "adequate directions for use" to mean directions that a lay person can follow. 21 C.F.R. 801.5. This interpretation was codified in 1952 (17 Fed. Reg. 6818), and has been consistent since passage of the Act in 1938. See *United States* v. *Articles of Drug*, 625 F.2d 665, 672 (5th Cir. 1980). An exemption from this lay standard of labeling is provided for prescription devices. 21 C.F.R. 801.109. The exemption includes a condition that the medical device be safe and effective when used by a practitioner. 21 C.F.R. 801.109(c).

2. The Toftness Radiation Device (TRD) is a plastic cylinder containing a series of lenses (Pet. App. 2). The proponents of the TRD claim that a chiropractor trained in its use can detect low level electromagnetic radiation emanating from a patient's body and thereby diagnose areas of neurological disturbance (*ibid.*).

The United States brought this action to condemn the TRD and enjoin its further use because it was "misbranded" within the meaning of the Act (21 U.S.C. 352(f)(1)). The district court found that the government had established misbranding as a matter of law by proving that the TRD was a device in interstate commerce that lacked adequate directions for use by a lay person (Pet. App. 23-24). The court instructed the jury that it was to find the TRD misbranded unless it concluded that the device qualified for an exemption from the Act's labeling

requirements (*id.* at 24). For the TRD to be exempt as a prescription device, petitioners thus would be required to carry the burden of proving its effectiveness (*id.* at 25). The district court entered judgment on the jury's general verdict for the government (*id.* at 34-37).

The court of appeals affirmed (Pet. App. 1-20). The court determined that the prescription device regulation is framed as an exemption from the labeling requirements and that this regulatory structure is consistent with the Act (*id.* at 14-16). In sustaining the district court's allocation of the burden of proof, the court relied (*id.* at 15-17) on this structure and on the government's disadvantage in gaining access to evidence on the issue of effectiveness. The court noted, for example, that in the present case petitioners attacked the testimony of government experts, who found the TRD to be "completely worthless in diagnosis," by arguing that the government experts lacked the special training available only at the Toftness Post-Graduate School of Chiropractic, Inc. (*id.* at 17).

3. The court of appeals' decision is correct and does not conflict with any decision of this Court or any other court of appeals. Further review is therefore unwarranted.

The court of appeals used two established criteria for determining how to allocate the burden of proof. First, a party claiming an exemption from a statutory requirement ordinarily must prove entitlement to the exemption. See *United States* v. *First City National Bank*, 386 U.S. 361, 366 (1967). Second, the burden of proof is usually on the party with better access to the relevant evidence. See *United States* v. *New York, N.H. & H.R.R.*, 355 U.S. 253, 256 (1957).

Petitioners do not dispute the soundness of these principles. Nor do they contest the court of appeals' conclusion that evidence regarding the effectiveness of prescription devices such as the TRD is generally more accessible to the manufacturer or distributor than to the government. Petitioners' sole argument is based on the other ground of the court of appeals' decision, *i.e.*, that petitioners should bear the burden of proof because they were claiming entitlement to the regulatory exemption for prescription devices (21 C.F.R. 801.109). Petitioners maintain that the regulations should have required the government to prove that prescription devices do not bear adequate directions for use, rather than requiring the manufacturer or distributor to prove entitlement to the exemption.

Petitioners' argument completely misconstrues the standards under which regulations are judged. The Secretary is authorized "to promulgate regulations for the efficient enforcement of [the Act]" (21 U.S.C. 371(a)). Thus, unless Congress has "directly addressed the precise question at issue," the proper inquiry is "whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984), slip op. 4-5. Moreover, the Secretary's judgment regarding the structuring of exemptions is entitled to particular deference in view of its long-standing character. *CBS, Inc.* v. *FCC*, 453 U.S. 367, 382 (1981). Cf. *NLRB* v. *Transportation Management Corp.*, No. 82-168 (June 15, 1983), slip op. 4-11 (noting discretion of NLRB to determine allocation of burden of proof). Here, the challenged regulation is plainly valid because it is "not contrary to either the letter or intent of the statute" (Pet. App. 16)

and is amply justified by the government's disadvantageous access to evidence regarding effectiveness.

The only authority petitioners offer for their position is *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981). Petitioners concede that references to the burden of proof in that case were dicta (Pet. 13). Neither the district court (Pet. App. 26 n.2) nor the court of appeals (*id.* at 13 n.4) had any trouble distinguishing *Evers*. A "passing comment" (Pet. App. 13 n.4) such as the one in that case does not create a conflict necessitating review by this Court.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

REX E. LEE
Solicitor General

SEPTEMBER 1984

☆ U. S. GOVERNMENT PRINTING OFFICE: 1984 421823 10039